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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/512,581	02/24/00	SOTO A	MBI-008

000959
LAHIVE & COCKFIELD
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HM12/0309

EXAMINER
RAWLINGS,S

ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/512,581	SOTO ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☒ Other: *Restriction Election facsimile sheet* .

DETAILED ACTION

1. Claims 1-67 are pending in the application and are currently subject to restriction.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Elections/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1, 2, 4-12, 47, 48, 49, and 51, in so far as the claims are drawn to an isolated nucleic acid molecule, a vector comprising said molecule, a host cell transfected with a vector comprising said molecule, a method of producing a polypeptide encoded by said molecule, a kit comprising a material for measuring AS3 RNA, said material comprising said molecule, and a method of isolating said molecule or a portion thereof, classified in class 536, subclass 23.1, class 435, subclass 320.1, class 435, subclass 325, class 435, subclass 69.1, and class 435, subclass 91.2, respectively. It is noted that claims 47 and 51 recite a kit for diagnosing a mammal and a kit for determining if a subject is at increased risk, respectively. However, this limitation is viewed as a recitation of intended use and therefore is not given weight in comparing and differentiating the various products claimed. Claims 47 and 51 read on the component of the kits *per se*, which is presumed to be the nucleic acid molecule according to claim 1.

Group II. Claim 3, drawn to an isolated nucleic acid molecule, classified in class 536, subclass 23.1. It is noted that the claim is incomplete, because the accession number is omitted. Therefore, since it cannot be ascertained what nucleic acid molecule is being claimed, it is presumed that the claim is drawn to a nucleic acid molecule that is distinct from the other inventions.

Group III. Claims 13-15, drawn to a polypeptide and a polypeptide further comprising heterologous amino acids, classified in class 530, subclass 350.

Group IV. Claims 16, 46, and 51, in so far as the claims are drawn to an antibody or a kit comprising the antibody, classified in class 530, subclass 387.1. It is noted that claim 46 recites a kit for diagnosing a mammal and that claim 51 recited a kit for determining if a subject is at increased risk. However, these limitations are viewed as recitations of intended use and therefore are not given weight in comparing and differentiating the various products claimed. Claims 46 and 51 read on the component of the kits *per se*, which is the antibody according to claim 16.

Group V. Claims 17-19, drawn to method for detecting the presence of a polypeptide, classified in class 435, subclass 7.1.

Group VI. Claims 20-22, drawn to a method of detecting the presence of a nucleic acid molecule and a kit, classified in class 435, subclass 6.

Group VII. Claims 23 and 24, drawn to a method for identifying a compound that binds to a polypeptide and/or modulates the activity of the polypeptide, classified in class 435, subclass 7.1.

Group VIII. Claim 25, drawn to method for modulating the activity of a polypeptide, classified in class 424, subclass 130.1.

Group IX. Claims 26 and 27, drawn a transgenic animal, classified in class 800, subclass 8.

Group X. Claims 28-30, drawn to a method of identifying a compound that modulates cell proliferation, classified in class 435, subclass 4.

Group XI. Claims 31, 33, and 34, drawn to a method of inhibiting the proliferation of a cell, classified in class 424, subclass 138.1.

Group XII. Claim 31, 32, and 35-38, in so far as the claims are drawn to a method of inhibiting cell proliferation in a mammal, classified in class 514, subclass 44.

Group XIII. Claims 39 and 66, in so far as the claims are drawn to a method for diagnosis comprising determining whether the AS3 gene is mutated, classified in class 204, subclass 450.

Group XIV. Claims 40-44 and 66, in so far as the claims are drawn to a method for diagnosis comprising measuring the expression level of the AS3 gene, classified in class 435, subclass 7.1 or class 435, subclass 6.

Group XV. Claims 50 and 66, drawn to a method for risk assessment comprising measuring the level of AS3 gene expression, classified in class class 435, subclass 7.1 or class 435, subclass 6.

Group XVI. Claim 52-56, drawn to a method of prognosis, classified in class 435, subclass 6 or class 435, subclass 7.1.

Group XVII. Claim 57-65, drawn to a method of treating cancer, classified in class 424, subclass 198.1.

Group XVIII. Claim 66, drawn to a method of risk assessment comprising determining if the AS3 gene is mutated, classified in class 204, subclass 450.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups I-IV and IX are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups I, V-VIII, and X-XVIII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

The inventions of Groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide of claim 13 could be used in a materially different process, such as in a method of modulating the activity of the polypeptide.

The inventions of Groups III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide of claim 13 could be used in a materially different process, such as in a method of identifying a compound that binds to the polypeptide.

The inventions of Groups I/III/IV/IX and I/V-VIII/X-XVIII are not at all related because the products of Group I/III/IV/IX are not specifically used in any of the claimed methods of Groups I/V-VIII/X-XVIII.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Elizabeth Hanley, Esq. on February 13, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax

phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Art Unit 1642

DONNA WORTMAN
PRIMARY EXAMINER

slr
March 1, 2001